

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2132023	(X3) Date Survey Completed 09/15/2020
Name of Provider or Supplier The Emergency Clinic At The Pearl	Street Address, City, State 2015 Broadway Street, Suite B, San Antonio, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory failed to have documentation of verifying new lots of quality control prior to use. The findings were: 1. A review of the laboratory's quality control records from February 2020 to July 2020 revealed the laboratory used the following lots of quality control material: a) Triage Total 5 Control (D dimer) Level 1: 03548 03547 03544 Level 2: 03573 03570 03567 03568 b) Triage Total 5 Control (Cardiac) Level 1: 03548 03544 03539 Level 2: 03573 03567 03568 03563 c) BRT Chemistry control (Met Lac 12) Lot: 1910004 1905012 2. The laboratory was asked to provide documentation of verifying each new lot of control material prior to use. No documentation was provided. 3. An interview with the technical consultant on 09/15 /2020 at 1145 hours in the office revealed the facility did not verify new lots of chemistry control material. This confirmed the findings.